Antimicrobial Stewardship Legislation and Policy Update
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Vizient

PCAST Report

1. Federal Investment and Leadership
2. Strengthening antibiotic resistance surveillance
3. Supporting development for new human antibiotics and alternatives in animal agriculture
4. Easing the burden of clinical trials
5. Push/pull mechanisms for developing new drugs
6. Advancing antibiotic stewardship and point of care diagnostics
7. Promoting stewardship in animal agriculture
8. Promoting international cooperation

Antibiotic Stewardship as a Condition of Participation
By the end of 2017, CMS should have Federal regulations (Conditions of Participation) in place that will require U.S. hospitals, critical access hospitals, and long-term care and nursing home facilities to have in place robust antibiotic stewardship programs that adhere to best practices, such as those contained in the CDC Core Elements for Hospital Antibiotic Stewardship Program recommendations. Similar requirements should be phased in rapidly for other settings including long-term acute care hospitals, other post-acute facilities, ambulatory, surgery centers, and dialysis centers.
Look to the Core Elements Document for a best guess

- Leadership commitment from administration
- Single physician leader responsible for outcomes
- Single pharmacy leader
- Educating providers on use and resistance
- Specific improvement interventions – IV to PO, indication for use, timeout
- Antibiotic use tracking
- Regular reporting on antibiotic use and resistance

http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html

Which Measures Are Likely Candidates for Inclusion in the CMS Conditions of Participation?

NHSN Annual Facility Survey - Antibiotic Stewardship

<table>
<thead>
<tr>
<th>Count of Elements</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
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<td>107</td>
<td>2.6</td>
</tr>
<tr>
<td>1</td>
<td>169</td>
<td>4.0</td>
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<tr>
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<tr>
<td>7</td>
<td>1628</td>
<td>38.9</td>
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Source: CDC Preliminary Data

CMS Conditions of Participation Update

- CMS discloses at ID week 2015 that the COPs have been cleared for release
- Quotes regarding timing
  - They should be out at the end of the year (2015)
  - They will be released in early 2016
  - They should be released by April 2016
  - Your guess is as good as mine –

Long Term Care Conditions of Participation

- Released for public comment on July 13 2015
- First major update since 1991
- Redefined LTCF infection prevention and control programs to include antibiotic stewardship
  - ASPs should include antibiotic use protocols and monitoring
- Much debate about who will be leading this program
  - Designated infection prevention and control officer (IPCO)
  - ID physician?
  - ID pharmacist?
  - Consultant pharmacist?
- Received over 7000 comments
- Final COPs not yet released

National Action Plan for Combating Antibiotic-Resistant Bacteria

Goals
1. Slow emergence of resistant bacteria and prevent the spread of resistant infections
2. Strengthen national One-Health surveillance efforts to combat resistance
3. Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria
4. Accelerate basic and applied research and development for new antibiotics, other therapeutics and vaccines
5. Improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control, and antibiotic research and development

https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf
National Strategy for Combating Antibiotic Resistant Bacteria – 2020 Goals

- All states will implement stewardship activities in healthcare settings
- All states will have established or enhanced regional efforts to reduce transmission of antibiotic resistant pathogens and improve appropriate antibiotic use in healthcare facilities across the continuum of care
- All federal facilities will have robust stewardship programs
- 95% of hospitals will report antibiotic use data to NHSN
- Reduce inappropriate use for monitored conditions/agents by:
  - 20% in-patient from 2014 levels
  - 50% outpatient from 2010 levels
- Increased oversight on the utilization of antibiotics in food production
- CDC and AHRQ will expand research

White House Antimicrobial Summit – June 2015

- Convened 150 key stakeholders across human and animal health sectors to discuss the increasing problem of antibiotic resistance
- **Human Health**
  - Session 1: Improving Inpatient Prescribing; Focus on Patients
  - Session 2: Improving Outpatient Prescribing; Focus on Families
  - Session 3: Improving Long-term Care Prescribing; Focus on Aging Population

Active Legislation in 2016

**Federal**
- 21st Century Cures Act

**State**
- California SB 994
  - Requirement of ASP in outpatient health facilities
  - Check for additional updates at [http://www.astho.org/state-legislative-tracking/](http://www.astho.org/state-legislative-tracking/)

JCAHO

Released Proposed Medication Management Standards for ASP (MM.09.01.01)
- Critical Access Hospital (CAH)
- Hospital Accreditation Program (HAP)
- Nursing Care Center (NCC)
- Ambulatory Health Care (ABH)
- Office Based Surgery (OBS)

Comment period closed December 30, 2015 – over 1000 comments received

JCAHO Proposed MM.09.01.01

<table>
<thead>
<tr>
<th>EP</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Leaders establish antimicrobial stewardship as an organizational priority.</td>
</tr>
<tr>
<td>2</td>
<td>Educate staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire and annually thereafter.</td>
</tr>
<tr>
<td>3</td>
<td>Educate patients, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics.</td>
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<tr>
<td>4</td>
<td>The organization has an antimicrobial stewardship multidisciplinary team that includes the following members, when available in the setting: Pharmacist(s), infection disease physician, infection preventionists (part time/consultant staff acceptable).</td>
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JCAHO Proposed MM.09.01.01

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| 5  | The organization’s antimicrobial stewardship program includes the following core elements:  
Leadership commitment  
- Action  
- Accountability  
- Tracking  
- Drug expertise  
- Reporting  
Education |
| 6  | The organization’s antimicrobial stewardship program uses organization-approved multidisciplinary protocols. |
| 7  | The organization collects and analyzes data on its antimicrobial stewardship program, including antimicrobial prescribing and resistance patterns. |
| 8  | The organization takes action on improvement opportunities identified in its antimicrobial stewardship program. |

National Quality Forum

- Selected “Advancing Antibiotic Stewardship in Healthcare” as a 2016 Initiative
- Formerly endorsed the Standardized Antibiotic Administration Ratio (SAAR) as a measure
- National Quality Partners Action Team
  - Developing a Practical Playbook to Advance Antibiotic Stewardship

Take Aways

- Federal policy has intensified the focus on improving the use of antibiotics in food production and human health
- The CMS Conditions of Participation (COPs) for antibiotic stewardship are expected to be released for comment soon with intent that they will be finalized and in place no later than the end of 2017
- Based on preliminary data from the NHSN survey, less than 40% of hospitals are prepared to meet these COPs

However, there still is much work to be done to ensure that hospitals and other health care organizations have implemented a program to promote judicious use of antibiotics in order to prevent unintended consequences and improve care

Payors

- Anthem-Blue Cross Blue Shield
  - Starting in 2016, a hospital’s performance to the CDC’s Core Elements for ASP will be included as part of their payment model
- Core Quality Measures Collaborative
  - Avoidance of antibiotic treatment in adults with acute bronchitis

Questions